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WOULD TRIAGE PREDICTORS PERFORM BETTER THAN FIRST-COME-
FIRST-SERVED IN PANDEMIC VENTILATOR ALLOCATION?

Short title: Pandemic Triage Predictor Performance

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Dr. Kanter conceived, designed; postulated, analyzed, and interpreted the data for the simulation study; drafted and wrote the submitted article; approves of the submitted version to be published; agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Abstract

Background - In a pandemic, needs for ventilators might overwhelm the limited supply. Outcome predictors have been proposed to guide ventilator triage allocation decisions. However, pandemic triage predictors have not been validated. This quantitative simulation study evaluated outcomes resulting from allocation strategies varying in their performance for selecting short stay survivors as favorable candidates for ventilators.

Methods - A quantitative simulation modeled a pandemic surge. Postulated numbers of potential daily admissions presented randomly from a specified population, with a limited number of available ventilators. Patients were triaged to ventilator care vs palliation, or turned away to palliation if no ventilator was available. Simulated triage was conducted according to a set of hypothetical triage tools varying in sensitivity and specificity to select favorable ventilator candidates, versus first-come-first-served allocation. Death was assumed for palliation. Survival or death was counted for ventilated patients according to the specified characteristic of each randomly selected patient.

Results - Triage predictors with intermediate quality performance resulted in a median daily mortality of 80%, similar to first-come-first-served allocation. A poor quality predictor resulted in a worse mortality of 90%. Only

a high quality predictor (sensitivity 90% & specificity 90%) resulted in a substantially lower 60% mortality.

Conclusions - Performance of unvalidated pandemic ventilator triage predictors is unknown and possibly inferior to first-come-first-served allocation. Poor performance of unvalidated predictors proposed for triage would represent an inadequate plan for stewarding scarce resources and would deprive some patients of fair access to a ventilator, thus falling short of sound ethical foundations.

ABBREVIATIONS

ICU \checkmark intensive care unit

%ile - percentile

INTRODUCTION

In a pandemic, needs for ventilators might overwhelm the limited supply. Triage of mechanical ventilators might be necessary in severe pandemics, whether based on formal allocation rules, or by de facto rationing as first-come-first-served ¹. A recent simulation study demonstrated potentially improved population outcomes in a pandemic if it were possible to distinguish a favorable subgroup for priority treatment ². Selecting patients likely to survive with brief ventilator support would improve survival rates among the current patients, and would improve ventilator availability for subsequent candidate patients.

Sensitivity and specificity are standard performance measures of criteria used to guide clinical decision-making. Although outcome predictors are available for critically ill populations ³⁻⁶, predictive tools necessary to select favorable individuals for ventilation have not been investigated or validated. In particular, sensitivity and specificity have not yet been evaluated as performance measures in published efforts to adapt population outcome predictors to individual patient triage. This quantitative simulation study evaluated the impact on population outcomes resulting from hypothetical triage prediction tools with varying sensitivity and specificity, for selecting

individuals for pandemic ventilator or palliative care assignment, compared with first-come-first-served allocation.

METHODS

Assumptions

A quantitative simulation study was conducted. A severe patient surge was considered in a hypothetical pandemic in which 10 new candidate patients presented for care in respiratory failure needing mechanical ventilation each day. A maximum of 15 ventilators were assumed available in a hypothetical intensive care unit (ICU) and no other facility was available to accommodate transfers.

A hypothetical population was postulated for the simulation having a 30% mortality rate (similar regardless of ventilator days), and a distribution of required ventilator days (for survivors and nonsurvivors) with median = 3 days, 75th percentile (mile) = 9.3 days. Daily admissions were randomly drawn from an infinite population represented by a specified population of 200 patients, with characteristics as shown in Figure 1. Random selection of daily patients permitted repeated inclusion of a patient with the same characteristics from the specified population distribution.

Simulated triage rules assigned ventilators (if a ventilator was available) or palliative care to new

candidate patients at the time of consideration for ICU admission. Alternatively, patients were assigned to a ventilator on a first-come-first-served basis (equivalent to random allocation) as long as a ventilator was available, while the rest were assigned to palliative care.

An arbitrary threshold was postulated to categorize hypothetical patients as favorable for ventilator treatment: those who would survive with fewer than 10 days of mechanical ventilation. The remainder of patients in the specified population were categorized as unfavorable for ventilation: those who would die despite mechanical ventilation (30% of the population) or those who would require 10 days or longer of mechanical ventilation (longer than the 75th %ile = 25% of the population). 7.5% of the specified population had both unfavorable conditions, death and long ventilator dependence (30% died x 25% long ventilator dependence = 7.5%). Therefore, the patients unfavorable for mechanical ventilation account for 47.5% of the population (30% died + 25% long ventilator dependence - 7.5% with both unfavorable conditions = 47.5%). Thus, favorable patients are 52.5% of the population (100% - 47.5% = 52.5%).

In order to evaluate the population impact of varying performance of predictors, a set of hypothetical imperfect triage predictive tools was postulated. The predictors

differed in their accuracy identifying patients as favorable or unfavorable for mechanical ventilation. Performance of predictors was defined (Figure 2) as sensitivity of triage exclusion criteria (the proportion of candidate patients unfavorable for mechanical ventilation correctly assigned to palliative care) and specificity of ventilator eligibility criteria (the proportion of candidate patients favorable for mechanical ventilation correctly assigned as eligible for mechanical ventilation). The hypothetical predictive triage tools included 1) A high quality predictor (90% sensitive and 90% specific), 2) an intermediate quality predictor (90% sensitive and 40% specific), 3) an intermediate quality predictor (40% sensitive and 90% specific), and 4) a poor quality predictor (40% sensitive and 40% specific). For comparison, 5) ventilator allocation without triage selection by first-come-first-served was also considered in the simulation.

For purposes of the simulation, other simplifying assumptions were made. Only patients needing mechanical ventilation were considered. In a pandemic, both infected and nonpandemic patients would have to be served. However, new candidate patients were considered to include an unspecified mix of pandemic and nonpandemic diagnoses, without distinguishing these in the specified study population. Ages of patients were not considered, and it was assumed that both pediatric and adult patients are

represented in the study. Each day's discharges or deaths were assumed to occur early in the day, preceding arrival of the day's new candidate admissions.

The Simulation

Each day, 10 new candidate patients were randomly selected from the specified population. According to the triage predictor used in each run of the simulation, patients actually unfavorable for ventilation were correctly assigned to palliative care 90% or 40% of the time, respectively, representing tools with a 90% or 40% sensitivity. Likewise, according to the triage predictor used in each run of the simulation, patients actually favorable for ventilation were correctly identified as eligible for ventilator care (if a ventilator was available) 90% or 40% of the time, respectively, representing tools with a 90% or 40% specificity. For first-come-first-served allocation, as many as possible of the 10 new daily patients were provided with ventilation.

The simulation evaluated typical and varying daily population outcomes, according to the chosen triage tool, over a 20 day steady state evaluation period. A preliminary 15 day period prior to the evaluation period served to populate the ICU with a steady state sample of patients, beginning from zero, selected according to each run's chosen triage tool. For all runs, ICU occupancy reached a steady

state occupancy level prior to the 20 day evaluation period (within each run's interquartile occupancy range). Each day's occupied ventilators were counted on the basis of the previous day's count, and the current day's new patient allocations, discharges, and deaths.

Random selection of patients from the specified population, and probability of assignment to treatment groups on the basis of hypothetical imperfect sensitivity and specificity was conducted in Excel (Microsoft Corporation). Daily occupancy and patient disposition were recorded and documented manually.

Simulated outcomes were considered as follows (Figure 3). When a ventilator was available for a candidate patient eligible for ventilation, survival or death was counted according to the specified characteristic of the patient randomly selected from the hypothetical population. When no ventilator was available for an eligible patient because all were already in use, simulated new candidate patients in respiratory failure would be turned away and provided with palliative care, counted as deaths in the simulation. Patients excluded from mechanical ventilation by triage criteria would also be provided with palliative care, and counted as deaths in the simulation. All survivals and deaths of candidate patients were counted on the day of their admission.

Analysis

Steady state daily events during the 20 day simulation were considered to be the units of analysis. Results were expressed as the daily median and interquartile range for each outcome. Daily outcomes included mortality (with or without mechanical ventilation), as well as numbers of patients assigned to a ventilator, eligible for ventilation but turned away because no ventilator was available, or triaged to palliative care. Differences in simulated daily mortality among triage predictor groups were evaluated by the nonparametric Kruskal-Wallis test, with differences considered to be significant if $p < .05$. The Kruskal-Wallis test determines whether multiple samples are consistent with the same distribution, or whether at least one of the samples appears to be drawn from a different distribution. The Kruskal-Wallis test does not identify which of the samples differs from the others.

Human subjects protection

The Institutional Review Board for Protection of Human Subjects at SUNY Upstate Medical University considered that this simulation study did not constitute human subjects research.

RESULTS

Daily mortality is shown in Figure 4. Predictors with intermediate quality performance (group 2 & 3) resulted in median daily mortality of 80%, similar to first-come-first-served allocation (group 5). A poor quality predictor (group 4) resulted in a slightly worse median daily mortality of 90%. Only a high quality predictor (group 1; sensitivity 90% & specificity 90%) resulted in a substantially lower mortality, daily median of 60%. Mortality differences among triage predictor groups were significant ($p < .05$). Median mortality rates of 60%, 80%, and 90% would result in 80, 40, and 20 survivors, respectively, among 200 candidate patients during the 20 day simulation.

Daily patient dispositions are shown in the Table. The high quality predictor provided ventilator availability for a daily median of 4 eligible patients/day (of a daily total of 10 candidates), accounting for the lower mortality rate. Intermediate and poor quality predictors as well as first-come-first-served allocation (groups 2-5) provided ventilator availability for a median of only 2-3 patients/day.

Differences in triage predictor performance accounted for substantial differences in reasons for deaths. First-come-first-served allocation (group 5) resulted in more patients turned away due to lack of a ventilator (median = 7 patients/day) than any of the other triage methods (groups

1-4; median = 0-5 patients/day). Triage predictors that erroneously assigned many favorable patients to palliative care (low specificity, groups 2 & 4) resulted in more patients excluded from ventilation by triage criteria (median = 7.5 & 5.5 patients/day, respectively) than tools with high specificity (groups 1 & 3; median = 4 & 2 patients/day, respectively). For the triage predictor with high sensitivity and low specificity (group 2) many candidate patients who would have benefitted from ventilation died after exclusion to palliative care according to erroneous triage criteria, despite the availability of ventilators on every one of the 20 simulated days. On the other hand, erroneous assignment of unfavorable patients to mechanical ventilation (low sensitivity, groups 3 & 4) resulted in more patients turned away due to lack of a ventilator (median = 5 & 3 patients/day, respectively) than tools with high sensitivity (groups 1 & 2; median = 2 & 0 patients/day, respectively).

Under the simulated conditions, the vast majority of deaths occurred as a result of patients turned away due to lack of a ventilator or as a result of exclusion by triage criteria. Few deaths occurred for patients accommodated for mechanical ventilation in any of the allocation groups (median = 0 to 1/day).

DISCUSSION

Implications

An ethically sound approach to pandemic ventilator allocation would steward scarce resources, maximize population survival, provide palliative care for each individual denied ventilator treatment. Balancing overwhelming needs and scarce resources requires planning, must be fair, and must be perceived as fair¹. Sets of triage predictors for pandemic ventilator allocation have been proposed^{7,8}. An international pediatric task force on mass critical care endorsed the potential utility of evidence-based triage predictors, but declined to propose specific guidelines, citing the lack of evidence validating predictive triage tools to identify patients favorable for mechanical ventilation⁹. An empirical attempt to validate one pandemic triage predictor revealed difficulties with interobserver inconsistencies, and deficiencies in predictive performance in a sample of adults¹⁰.

A test with 90% sensitivity and specificity is rare in any clinical field. No published validation of existing ICU population mortality predictors demonstrates a 90% sensitivity and specificity at any threshold. Further, no published ICU population outcome predictor estimates mortality risk together with duration of ventilator dependence. The present simulation study demonstrates that triage predictors that do not perform with high quality in identifying pandemic patients favorable for ventilation may

result in population outcomes no better than first-come-first-served allocation. A predictor that performs poorly might result in outcomes even worse than first-come-first-served allocation.

Limitations

The present report is intended to explore potential hazards in the application of unvalidated ICU population outcome predictors to individual patient triage assignment for pandemic ventilator allocation. The simulation is not designed to represent all the variables in a real pandemic, and cannot provide decision support in real triage situations.

Validity of simulations depends on assumptions. Assumptions about the surge and study population were consistent with the following historical evidence. A surge of 10 patients per day for an ICU providing 15 ventilators corresponds to a daily rate of 0.67 patients/ventilator. This compares with US national daily rates of adult admissions/adult ICU beds = 0.26¹¹, and pediatric admissions/pediatric ICU beds = 0.17¹² (2.5-4 times higher than the nonpandemic ICU admission rates for adults and children, respectively). The simulated patient surge was larger than any regional sustained emergency ever encountered during the modern critical care era. Recent historic pandemics have required "ordinary surge" or

“contingency standards of care” rather than “crisis standards of care” warranting ventilator triage^{7,9}.

The assumed 30% mortality rate in the specified hypothetical population was substantially higher than representative nonpandemic ICU mortality for children = 3.7–4.9%^{5,6} or adults = 13.5–23%^{3,4}, and was also higher than H₁N₁ pandemic mortality rates for adults and children combined = 17.3–22.6%^{13,14}. It is reasonable to assume that in a severe pandemic, an ICU would be filled with sicker patients than in usual circumstances, and that crisis standards of care might worsen mortality for any given illness severity¹⁵.

The assumed ventilator days for each patient in the specified study population (median = 3 days, 75th %ile = 9.3 days) were longer than reported nonpandemic adult ICU stay (median = 2.14 days, 80th %ile = 5 days)¹⁶ and pediatric ICU stay (median = 2 days, 75th %ile = 3 days)¹⁷, but were shorter than combined pediatric and adult H₁N₁ pandemic ICU stay (median = 7 days, 75th %ile = 13.4 days)¹³, and combined pediatric and adult H₁N₁ pandemic ventilator days (median = 12 days, 75th %ile = 20 days)¹⁴. As assumed in the present study, H₁N₁ pandemic surveillance¹⁴ showed pediatric and adult mortality rates were similar across shorter and longer durations of mechanical ventilation.

The threshold chosen to identify patients favorable for ventilator allocation was arbitrary for the simulation, but was adequate to gain a mortality advantage if triage prediction was of high quality. If the ratio of patients per ventilator varies, the results of any triage selection process would differ. For a larger surge, optimal triage thresholds would involve more restrictive criteria for ventilator allocation.

The use of statistical analysis in quantitative simulations is appropriate to describe patterns that emerge as a result of a random process. The use of statistical tests to determine the "significance" of differences in outcome among multiple treatment groups is questionable, as differences are so dependent on the multiplicity of assumptions necessary to create the quantitative model. In this simulation study mortality differences among the triage prediction groups were substantial. If such patterns were observed in an empirical population sample, differences would be larger than expected by chance alone. All else equal, differences would reasonably be attributed to varying triage predictor performance. More important in simulations is the demonstration of concepts and trends that should stimulate empirical efforts to improve policy and practice.

Some simplifying assumptions expedited the simulation although they were not intended to anticipate a particular

pandemic. Since they applied to all groups, simplifications did not bias the results. For purposes of the simulation, it was not necessary to detail clinical criteria that would constitute triage predictors. No basis was postulated to explain the differing performances among the hypothetical predictive tools. The simulation only considered triage at the time of initial evaluation of ventilator candidates, and did not address reevaluation and withdrawal of care after a trial of mechanical ventilation ¹.

Next steps

This simulation suggests a research and policy agenda necessary to implement pandemic ventilator allocation. The utility of population outcome predictions in critical care has usually been in quality improvement or risk adjustment in research. No experience is available in use of outcome predictors to guide triage decisions for individuals. Triage allocation tools will require converting continuous population mortality risk together with days on ventilator predictions into the discrete categories of ventilator versus palliation assignments for individual patients. Evidence to guide pandemic triage must be derived from pertinent reference populations prior to the pandemic. Preliminary empirical efforts to identify short stay survivors have recently been reported ¹⁸. A methodology is necessary to determine optimal thresholds converting population predictions to triage categories, as a function of the balance between needs and existing resources.

Validation of population predictions must determine sensitivity and specificity in identifying patients favorable and unfavorable for pandemic ventilation at the threshold chosen for triage assignment.

In an actual pandemic, performance of triage predictors will differ from that in reference populations used to derive the predictors. In pandemic conditions, populations, disorders, and therapy will differ from conditions in the prepandemic derivation set of patients. Therefore, public health leaders must be responsible to revise and revalidate triage predictors and thresholds on the basis of real-time evidence collected during the pandemic. In particular, real time adjustments would be essential to avoid erroneous and frequent denial of ventilator treatment according to excessively restrictive triage criteria even when a ventilator was available, as was observed in simulation group 2. Low specificity of the triage predictor (many errors of type c in Fig 2) would unnecessarily deprive patients of available ventilator care and must be avoided.

CONCLUSION

Performance of unvalidated pandemic ventilator triage predictors is unknown and possibly inferior to first-come-first-served allocation. Poor performance of unvalidated predictors proposed for triage would represent an inadequate

plan for stewarding scarce resources and would deprive some patients of fair access to a ventilator, thus falling short of sound ethical foundations. It remains unclear whether it is possible to formulate triage predictions on the basis of observable characteristics that would improve upon random patient selection in a pandemic surge.

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Figure 1.

Proportion of specified hypothetical population with indicated number of ventilator days until death or successful weaning from ventilation. Survival is indicated by open bars, death is indicated by solid bars. Median duration of ventilation = 3 days, 75%ile = 9.3 days.

Figure 2.

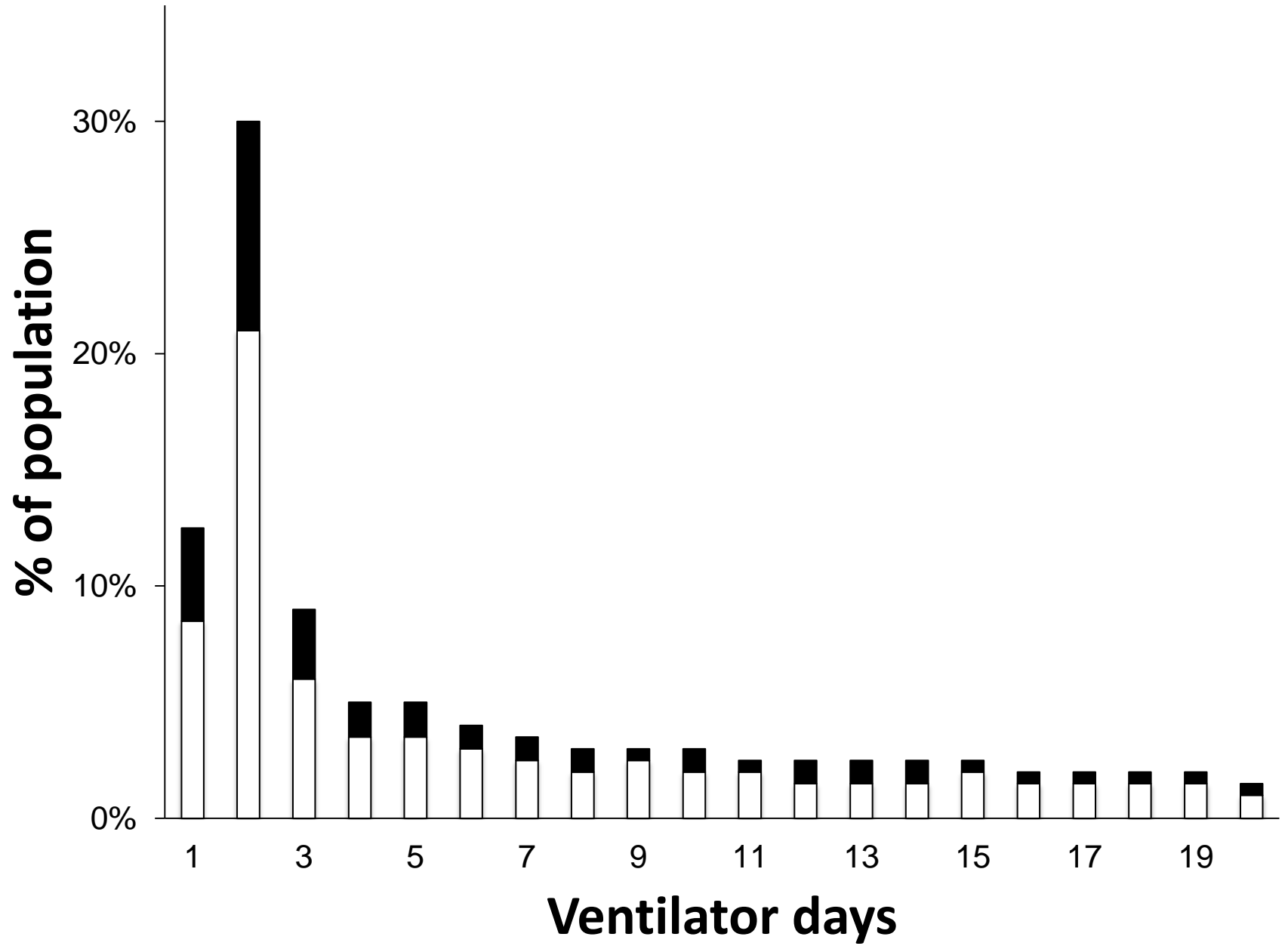
Relationship between actual categories in specified population and predicted triage categories. The categories are "favorable" for mechanical ventilation, or "unfavorable" warranting triage to palliative care. Quality of hypothetical triage predictor performance is described by sensitivity and specificity.

Figure 3.

Simulated triage allocation protocol and outcomes.

Figure 4.

Simulated daily mortality rate (median, interquartile range) for triage predictors: 1) High quality (sensitivity 90%, specificity 90%). 2) Intermediate quality (sensitivity 90%, specificity 40%), 3) Intermediate quality (sensitivity 40%, specificity 90%), 4) Poor quality (sensitivity 40%, specificity 40%), 5) First-come-first-served (random).



Actual Population Categories

Unfavorable Favorable

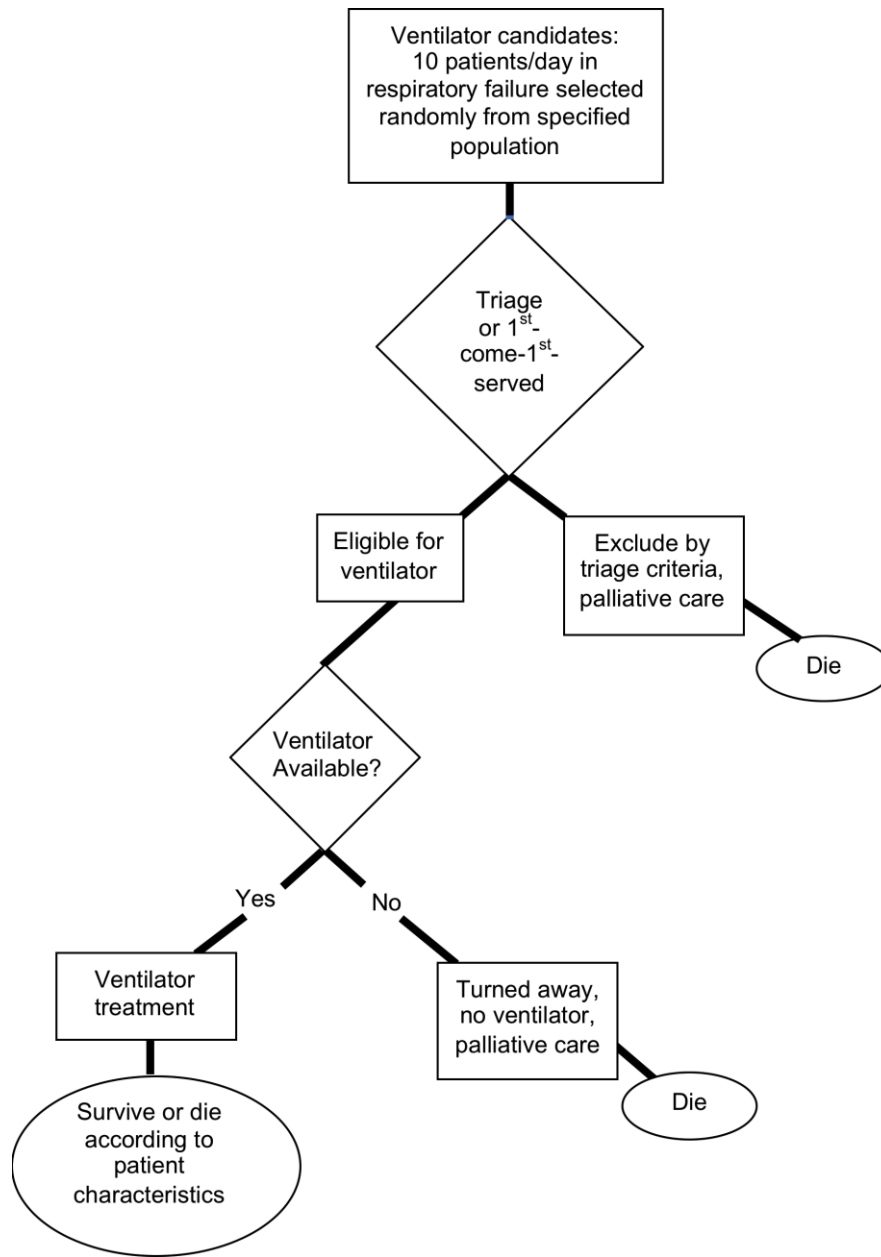
Predicted Triage Categories

Favorable Unfavorable

Correctly assigned to palliative care (a)	Erroneously assigned to palliative care (c)
Erroneously assigned to mechanical ventilation (b)	Correctly assigned to mechanical ventilation (d)

$$\text{Sensitivity} = a/(a+b)$$

$$\text{Specificity} = d/(c+d)$$



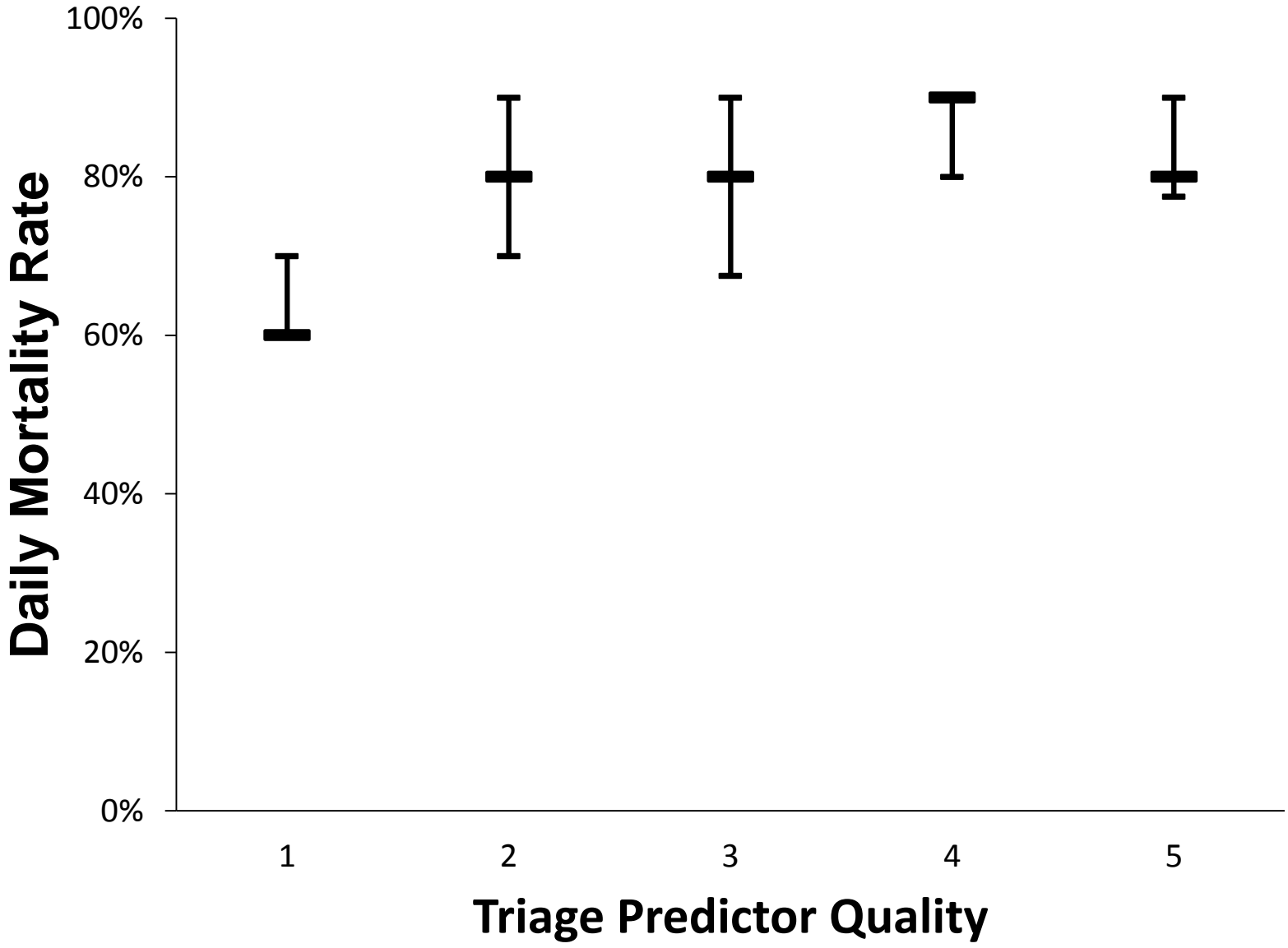


Table: Daily patient disposition with varying performance of triage predictors

Median numbers of patients (interquartile range), of total 10 patients/day

Triage predictors	High quality Sensitivity 90% Specificity 90% Group 1	Intermediate quality Sensitivity 90% Specificity 40% Group 2	Intermediate quality Sensitivity 40% Specificity 90% Group 3	Poor quality Sensitivity 40% Specificity 40% Group 4	First-come-first-served Random Group 5
Eligible patient accommodated for ventilator if ventilator available	4 (3-5)	2.5 (2-3)	3 (2-4)	2 (1-3)	3 (2-4)
Turned away no ventilator	2 (1-3)	0 (0-0)	5 (3.75-6)	3 (1.75-4)	7 (6-8)
Triaged to palliative care	4 (3-5)	7.5 (7-8.25)	2 (1-3)	5.5 (4-6)	Not applicable
Died on ventilator	0 (0-0)	0 (0-0.25)	0 (0-1)	1 (0-1)	1 (0-1)